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| 10/052,061 | 01/16/2002 | Nathan K. Olivas | 499962000700 | 1473 |

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| EXAMINER |
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KRUSE, DAVID H

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| ART UNIT | PAPER NUMBER |
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1638

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DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Applicati n N .

10/052,061

Applicant(s)

OLIVAS ET AL.

Examin r

David H Kruse

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-- The MAILING DATE f this c mmunication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 5, 6 and 8 is/are allowed.
- 6) ☒ Claim(s) 4, 9 and 10 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Specification

1. At pages 1, 2 and 12 of the specification, the Abstract on page 19 and claim 1, the information regarding the ATCC deposit number and date is incomplete. Applicant is reminded that upon notice of allowance, amendments to the specification and the claims must be filed under 37 CFR § 1.312, before or at the time of payment of the issue fee for the instant application to perfect compliance with 37 CFR §§ 1.801-1.809. In addition, the address of the American Type Culture Collection has changed and should be corrected in the specification (see page 12).

Drawings

2. The drawing originally filed is approved by the Examiner.

Claim Objections

3. Claim 7 is objected to because of the following informalities: Claim 7 lacks an article of language and should read -- A tissue culture --. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 4, 9 and 10 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a F1 hybrid *Lactuca sativa* having Pacer as a parent, and a *Lactuca sativa* selected from progeny of a plant growth from the seed of the exemplified Pacer variety deposited at ATCC that are phenotypically distinguishable from the parent plant.

Applicant describes a *Lactuca sativa* plant named 'Pacer'.

Applicant does not describe the genus of F1 hybrids having 'Pacer' as a parent, nor does Applicant describe phenotypically distinguishable progeny plants.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

6. Claims 4, 9 and 10 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims a F1 hybrid *Lactuca sativa* having Pacer as a parent, and a *Lactuca sativa* selected from progeny of a plant growth from the seed of the exemplified Pacer variety deposited at ATCC that are phenotypically distinguishable from the parent plant.

Applicant teaches a *Lactuca sativa* plant named 'Pacer'.

Applicant does not teach the genus of F1 hybrids having 'Pacer' as a parent, nor does Applicant teach phenotypically distinguishable progeny plants.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has provided limited guidance for how to make and use the claimed genus of F1 hybrids of the exemplified *Lactuca sativa* plant 'Pacer' and phenotypically distinguishable progeny plants thereof. The art teaches that phenotypic characteristics of *Lactuca sativa* L. var. *capitata* L. vary greatly from cultivar to cultivar (see De Vries *et al* 1994, Plant Systematics and Evolution 193: 125-141, in particular Figure 2 on page 130 and Figure 3 on page 133). Applicant's teachings are limited to the unique combination of morphological and physiological characteristics of the exemplified variety 'Pacer' that makes it useful as compared to other *Lactuca sativa* plants or progeny of said exemplified variety. It is well known in the art that *Lactuca sativa* is typically a self-pollinating plant, and that fixing useful characteristics of an outcross requires multiple generations of selection to produce a useful, stable lettuce plant variety. In addition, it was well known in the art at the time of Applicant's invention that one of skill in the art cannot predictably predetermine how the genomes of two different parental *Lactuca*

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plants will recombine to make a new *Lactuca sativa* plant that is useful. Given the wide variety of other *Lactuca sativa* plants that one of skill in the art can use to cross with the exemplified lettuce variety 'Pacer', in addition to the number of species of *Lactuca* that can be used to cross with *Lactuca sativa*, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to produce a myriad of F1 progeny using Applicant's 'Pacer' lettuce variety as one of the parents to produce a useful lettuce plant.

At claims 9 and 10, Applicant states on page 7, paragraph 0031 of the specification that the exemplified 'Pacer' variety is true to type, uniform, stable and free from variants. Claim 8 upon which the instant claims are dependent does not specifically recite any crossing step with another *Lactuca sativa* plant, and given the nature of self-fertilization as discussed above, would not enable phenotypically distinguishable progeny plants, if Applicant's statement were true.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4, 9 and 10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ryder *et al* (HortScience 1994, 33(5): 903-904).

Ryder teaches a vanguard type crisphead lettuce variety designated 'Tiber' in addition to multiple breeding lines of crisphead lettuce.

Ryder does not teach an F1 progeny plant of Applicant's exemplified 'Pacer' variety of lettuce, or progeny of 'Pacer' in general.

The *Lactuca sativa* plant of the instant claims would have been *prima facie* obvious in view of the teachings of Ryder *et al* and would have been indistinguishable from the claimed progeny given the wide variety of second parental breeding partners one of ordinary skill in the art could have used to cross with Applicant's exemplified 'Pacer' lettuce variety, having a wide variety of phenotypic characteristics. Ryder teaches multiple *Lactuca sativa* plant breeding lines on page 904, left column, which have vanguard type characteristics that would have improved texture, head shape, growth habit and shelf life as taught by Applicant (page 17, paragraph 0077 of the specification). Given the teachings of Ryder, one of ordinary skill in the art at the time of Applicant's inventions would have had a reasonable expectation of success in producing a *Lactuca sativa* plant having the desired characteristics and would have been motivated to produce such a plant because of its desirable characteristics, that would have been indistinguishable from progeny of Applicant's 'Pacer' variety. Claims 9 and 10 are included in this rejection because the method of making at claim 8 does not exclude crossing with another *Lactuca sativa* plant(s) over multiple generations to produce a phenotypically distinguishable progeny plant from the parent plant, that being Applicant's 'Pacer' *Lactuca sativa* plant.

Conclusion

9. Claims 1-3 and 5-8 are free of the prior art which neither teaches nor fairly suggests a *Lactuca sativa* plant or seed having all of the morphological and physiological characteristics of Applicant's 'Pacer' lettuce variety or a method of using same.
10. Claims 1-3, 5, 6 and 8 are allowed.
11. Claim 7 is objected to.
12. Claims 4, 9 and 10 are rejected.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'David H. Kruse', with a stylized, cursive script.

David H. Kruse, Ph.D.
16 June 2003